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Epidemiology of Mobile Home Formaldehyde Vapor Concentration and Residents' Health Status

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16. ABSTRACT

A home age stratified random sample cohort of 100 homes less than three years old and 37 homes of more than three years of age (mean 67 months) were enrolled and followed prospectively at monthly intervals. Formaldehyde air measurements ranged from below detection (0.1 ppm) to 2.84 ppm. The average monthly concentration from homes less than three years old was 0.54 ppm and 0.19 ppm from homes older than three years. Regression modeling found that the log of home age was the best environmental parameter for predicting formaldehyde levels. A total of 2,423 monthly self-administered symptom questionnaires were completed by the 288 persons in the homes which remained under study for six or more months. Stepwise logistic regression analysis was performed. A positive dependency of both burning eyes and watery eye symptom logits on the log formaldehyde exposure parameter was demonstrated. A positive relationship with respondents' age was also seen. Dry/sore throat, swollen glands, and diarrhea logits exhibited a lesser dependency on formaldehyde exposure. Cough, phlegm, and headache were related to cigarette smoking but not to formaldehyde. Fifty-three adults participated in clinical examinations. Evidence of ocular or nasal irritation was more prevalent among those from households with the higher formaldehyde levels (five of nine above 0.8 ppm) than those from the lower level homes (10% among those less than 0.4 ppm).

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THE EPIDEMIOLOGY OF MOBILE HOME FORMALDEHYDE VAPOR CONCENTRATION AND RESIDENTS' HEALTH STATUS

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EXECUTIVE SUMMARY

Under the TOSCA Section 28 cooperative agreement with Wisconsn, three epidemiologic sampling methodologies available to the Division of Health were evaluated to select the most feasible method of enrolling mobile home residents for studies of formaldehyde (HCHO) concentration measurements and construction, environmental factors and health status. Utilizing property tax records, an age (home) stratified, random sample cohort of 100 homes less than 3 years old and 37 homes of more than 3 years of age (mean 67 months) were enrolled and followed prospectively at monthly intervals. A total of 976 monthly home visits were made (77% of homes had 6 or more monthly visits).

A total of 1874 air samples, 730 blanks and 573 impinger blanks were analyzed. Formaldehyde air measurements ranged from below detection (0.1 ppm) to 2.84 ppm. The average monthly concentration from homes less than three years old was 0.54 ppm and 0.19 ppm from homes older than three years. Regression modeling found that the log of home age was the best environmental parameter for predicting formaldehyde levels.

A total of 2,423 monthly self-administered symptom questionnaires were completed by the 288 persons in the homes which remained under study for 6 or more months. Upper respiratory symptoms were the most common (centering around 40%) and the mucous membrane symptoms clustered about the 25% frequency. Stepwise logistic regression analysis was performed. A positive dependency of both burning eyes and watery eye symptom logits on the log formaldehyde exposure parameter was demonstrated. A positive relationship with respondents' age was also seen. Dry/sore throat, swollen glands and diarrhea logits exhibited a lesser dependency on formaldehyde exposure. Cough, phlegm and headache were related to cigarette smoking but not to formaldehyde.

Fifty-three adults participated in clinical examinations. Evidence of ocular or nasal irritation was more prevalent among those from households with the higher formaldehyde levels (5 of 9 above 0.8 ppm) than those from the lower level homes (10% among those less than 0.4 ppm). Pulmonary function abnormalities were only associated with cigarette smoking.

Laboratory evaluation of analytic methodologies were performed and the NIOSH P & CAM 125 method with two modifications utilized (sodium bisulfite as absorbing reagent instead of distilled water and the NIOSH sodium sulfite titration instead of the iodine method for standardization). Precision and accuracy determinations for the method were performed. The coefficients of variation for the sampling and analytical procedures was calculated at 32% at 0.03 ppm to 5% at 0.4 ppm. Because of the high relative error at the low concentrations (less than 0.1 ppm) 0.1 ppm was considered as the detection limit for the method as used during the project.

I. Assessment of Cooperative Agreement (TSCA Section 28) Overall Program Objectives

Although Wisconsin's original toxic substances cooperative agreement proposal included a broad range of timely topics of importance to both the state and the EPA, the final agreement focused priority upon assessing the potential health risks from exposure to indoor contaminants, most specifically formaldehyde. The agreement assisted Wisconsin to support expert professionals, and provided the necessary technical equipment to scientifically evaluate and characterize the health related questions being raised by state residents, legislators and the medical community. The agreement also helped the state attract other research scientists to join the core staff established by the agreement. Without the assistance of this agreement the state would have been seriously handicapped in responding appropriately to the complexities of the formaldehyde issue. The results of the agreement emphasize the importance of states being able to dedicate two or three individuals to address specific problem areas of mutual importance to states and the federal government. It is encouraging that a program of modest size was able to have not only a local, but also a national impact. The expertise gained by the program staff was sought and utilized by more than 20 states faced with similar needs but who were unable to mobilize a similar program. Preliminary results have also been utilized by HUD and CPSC. Interstate cooperation and collaboration eliminated some redundancy in state activities and avoided the necessity of investing scarce dollars and time in "reinventing the wheel."

Perhaps the best measure of the utility and success of the cooperative agreement is the fact that all staff hired under the agreement have been moved into corresponding state funded permanent positions created as a result of the success of the project and the state Legislature's recognition of the need for continuing such activities. In the current state budgetary period, these were among the only "growth" positions in the Division of Health. Thus the programmatic concepts in the agreement will continue well beyond the expiration of the contract and its funding. This would not have been possible without the "seed" money and direction of the TSCA Section 28 cooperative agreement. Throughout the agreement period EPA Region 5 has frequently called upon the state's Section of Environmental and Chronic Disease Epidemiology which was founded on the Section 28 agreement to assist in the resolution of other issues brought to EPA's attention but also of importance to Wisconsin. We expect this cooperative professional interaction to continue.

II. Objectives of Study

It was agreed that the specific project conducted under the cooperative agreement would have the following objectives.

1. To evaluate the feasibility of different epidemiologic methodologies; to select and implement the most appropriate study design.

   A. Quantify the concentration of formaldehyde in the air of representative residential mobile homes in Wisconsin.

   B. Identify and investigate possible household construction and environmental factors which might influence the concentration of formaldehyde found in mobile homes.

   C. Assess the current and past health status of mobile home residents and investigate possible associations of health effects and formaldehyde concentrations.

2. Evaluate different laboratory methodologies for collection and analysis of formaldehyde; establish laboratory and field quality control procedures to assess accuracy and reproducibility of study formaldehyde air samples; establish inter-laboratory quality control procedures.

III. Development of Study Protocol

During the first year of the agreement several different epidemiologic methodologies were evaluated before finalizing the main project protocol. Each design considered had different scientific advantages but each had implementation drawbacks which had to be evaluated. The final goal was to enroll a study population identified in a random manner and which would have a sufficient range of formaldehyde exposure levels to facilitate investigation of associations of health status and exposure levels.

The first methodology evaluated was a naturalistic probability sample of all mobile home parks and home sites in the state (sampling framework outlined in Table 1). A pilot sample was drawn and investigated to test the feasibility of this methodology. Prior to beginning, milestones were established for rejecting the methodology.

TABLE 1

MOBILE HOME INDOOR AIR QUALITY STUDY--FLOW CHART OF EVENTS

Using mobile home park registration lists, select pilot sample(s) to obtain 100 homes for feasibility study.

|

Map randomly selected mobile home parks for random selection of homes in park; leaflet park, field staff solicits household cooperation in person.

|

Sequentially analyze incoming samples to determine study efficacy.

|

Draw total sample of parks for full study.

Suspend study if design yields insufficient HCHO exposure gradient, poor response rate.

|

Map parks, select 1,100 homes for full study (yield 800 homes).

|

Leaflet homes, solicit household cooperation in person.

|

Take indoor HCHO measurement (1 time sample) health status assessed by follow-up questionnaire over the telephone.

|

Statistical analysis of data.

While all mobile home parks and sites in the parks could be detailed and sample sites selected, contact with owners and ultimate participation was low (65 out of 208 pilot sites) making the effort required to enroll the 800 desired homes beyond the time, manpower and funding of the project. With only a park lot number and no resident names, addresses or telephone numbers, the field staff had difficulty making direct contact with many of the sample homeowners. This was especially true for the many homes which turned out to be seasonal or weekend vacation homes. The second reason for deciding this methodology needed to be modified was that among the 65 homes sampled, the observed formaldehyde exposure gradient was less than desired for our health effects analysis. The majority of homes were more than three years old and the formaldehyde concentration distribution skewed toward the lower limit of detection. Although valuable information was obtained from the pilot study, its design was not selected as the best procedural method for obtaining a large formaldehyde concentration gradient.

The second methodologic design utilized the mobile home retailers as the source of identifying and enrolling study homes. The intent was to interview and clinically characterize the householders before and after they moved into their mobile home. The proposed study flow chart is outlined in Table 2. Initially the Wisconsin Manufactured Housing Association supported the study, but when participation was solicited from the individual dealers, only a small number agreed to participate. Working with this small group would not have provided sufficient homes. Thus this study design was also rejected.

After determining that the initial two study designs were unsuitable and could not be implemented in a manner consistent with the agreement constraints of time, funding and personnel and still fulfill the desired subject participation and scientific criteria established, a modified protocol was developed incorporating the portions of each of the first designs which were found feasible. The full-scale program was initiated in March, 1980. A summary flow chart is provided in Table 3.

IV. Summary of Implemented Epidemiologic Protocol

The final project design utilized a stratified random sampling procedure and prospective observation with enrolled homes visited once a month for six or more consecutive months; followed by a final sample at the one year anniversary. The monthly visits utilized identical staff, procedures and practices for each visit. Neither the field staff nor the participant families were given the sample or questionnaire results prior to the completion of all of the testing.

TABLE 2

MOBILE HOME INDOOR AIR QUALITY STUDY--FLOW-CHART OF EVENTS

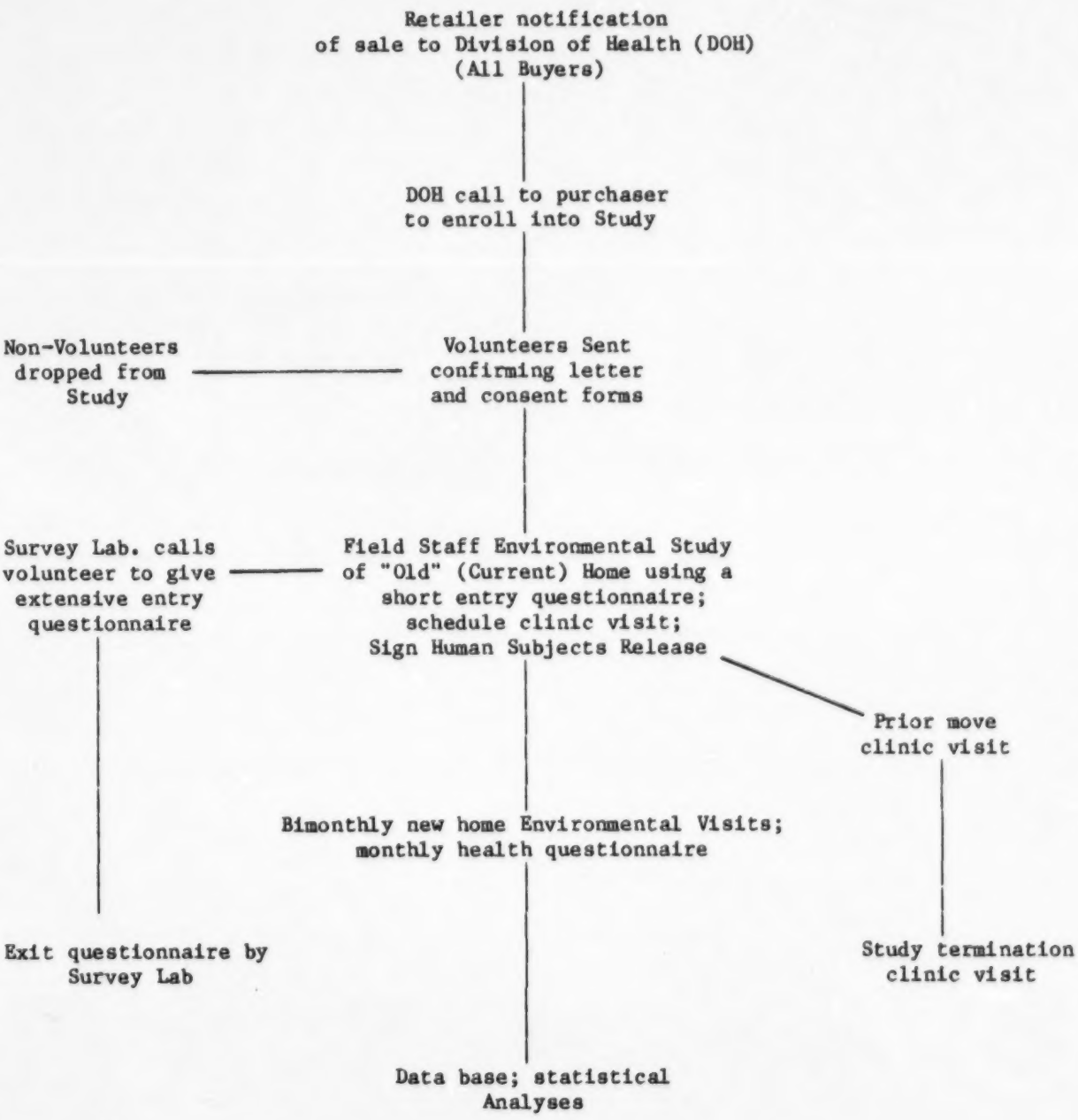
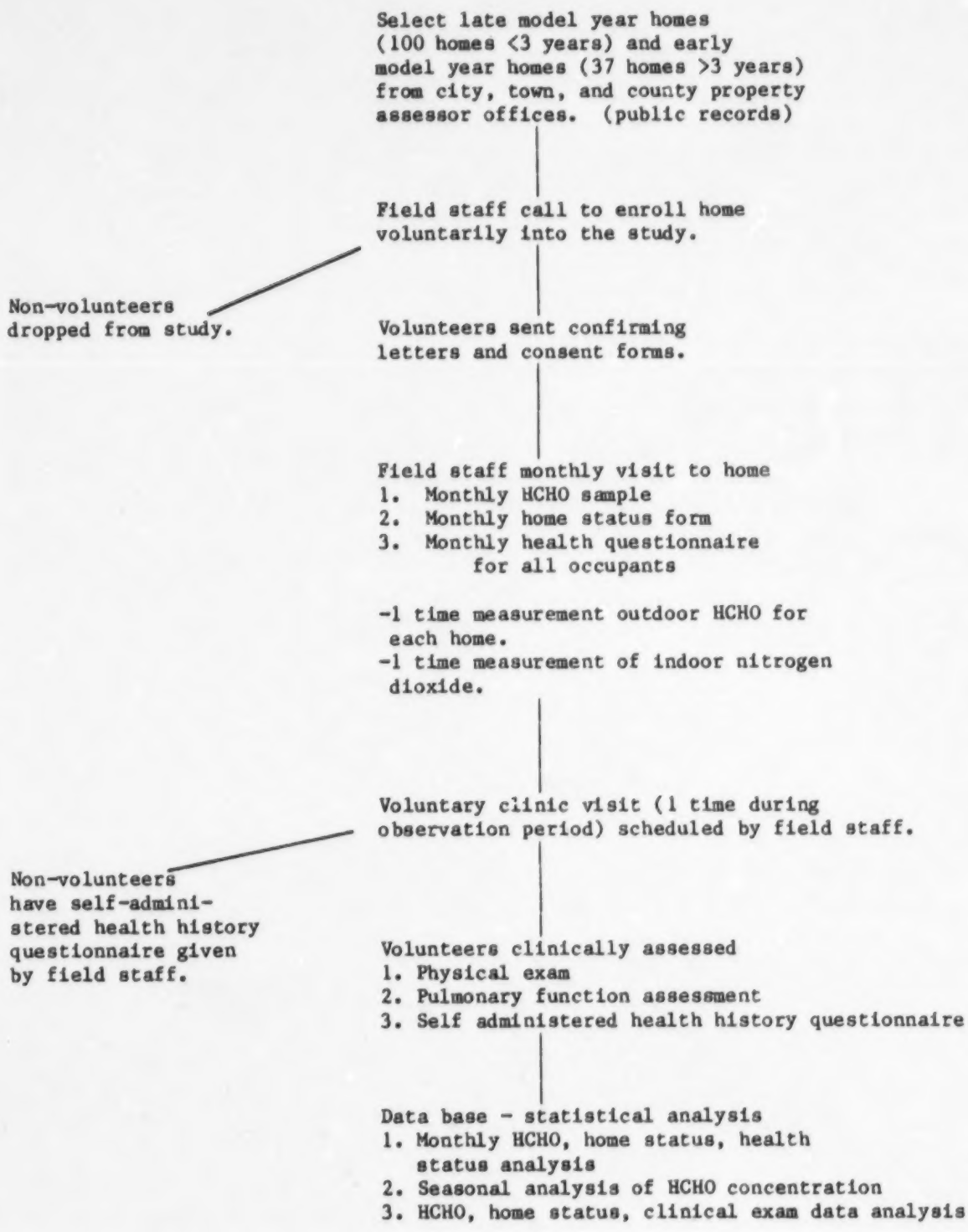

Retailer notification of sale to Division of Health (DOH) (All Buyers)
DOH call to purchaser to enroll into Study
Non-Volunteers dropped from Study
Volunteers Sent confirming letter and consent forms
Survey Lab. calls volunteer to give extensive entry questionnaire
Field Staff Environmental Study of "Old" (Current) Home using a short entry questionnaire; schedule clinic visit; Sign Human Subjects Release
Prior move clinic visit
Bimonthly new home Environmental Visits; monthly health questionnaire
Exit questionnaire by Survey Lab
Study termination clinic visit
Data base; statistical Analyses

TABLE 3

MOBILE HOME INDOOR AIR QUALITY STUDY--FLOW CHART OF EVENTS


Select late model year homes (100 homes <3 years) and early model year homes (37 homes >3 years) from city, town, and county property assessor offices. (public records)
Field staff call to enroll home voluntarily into the study.
Non-volunteers dropped from study.
Volunteers sent confirming letters and consent forms.
Field staff monthly visit to home
1. Monthly HCHO sample
2. Monthly home status form
3. Monthly health questionnaire for all occupants
-1 time measurement outdoor HCHO for each home.
-1 time measurement of indoor nitrogen dioxide.
Voluntary clinic visit (1 time during observation period) scheduled by field staff.
Non-volunteers have self-administered health history questionnaire given by field staff.
Volunteers clinically assessed
1. Physical exam
2. Pulmonary function assessment
3. Self administered health history questionnaire
Data base - statistical analysis
1. Monthly HCHO, home status, health status analysis
2. Seasonal analysis of HCHO concentration
3. HCHO, home status, clinical exam data analysis

A. Final Study Population Selection Methodology

Field offices and staff were located in three geographical areas of the state (Madison, Green Bay and Eau Claire). Each office contacted city and town assessors in their area for lists of mobile homes. Staff were able to utilize the statewide listing of mobile home parks developed during the previous design assessments and concentrate on cities or towns where mobile home parks were known. The lists generated were ordered by age of the mobile home and proximity to the field office. To minimize staff travel time, owners were called and invitations offered beginning with those parks closest to the offices. The goal was to enroll approximately 30 homes in each area. To assure a sufficient formaldehyde exposure gradient, only homes less than three years old were selected. Selection and enrollment began in March, 1980 and continued until July, 1980. The majority (78%) were enrolled and had their initial visit by May 31, 1980.

B. Comparison Group for Symptom Assessment and Clinical Studies

The pilot study from the first design evaluated confirmed that older mobile homes (greater than 3 years old) have significantly lower levels of formaldehyde than new homes. It was decided to use such homes as a comparison group. They were most appropriate since most would share the same socioeconomic and demographic characteristics as the study population except for formaldehyde exposure. Additionally, neither the participants nor the field staff would know which group were controls and which the study population. Media impact on attitudes would also be similar since all mobile homes were being portrayed as "at risk," not just the new homes. A target of approximately 10 comparison homes was sought for each field office.

C. Symptom Assessment

Each month at the time of the sampling visit, each family member was asked to complete a brief, self-administered health history and symptom questionnaire covering the preceding month. Compliance was excellent and a total of 2,423 questionnaires were completed during the study.

Midway through the prospective period, each individual was asked to complete a much more detailed health questionnaire requiring 30-40 minutes to complete. As might be expected, compliance with that questionnaire was much more difficult and only 170 (60%) questionnaires were returned.

D. Clinical Assessment

Midway through the observation period, each individual was offered and encouraged to participate in clinical examinations

conducted two days in each of the field office areas. At the clinic a physical examination and pulmonary function tests were performed. None of the clinic staff were aware of the levels of formaldehyde in the homes or which examinees were study subjects and which from the comparison group. A total of 53 adults and 23 children were examined.

V. Results of Epidemiologic Survey

A total of 137 mobile homes were voluntarily enrolled into the study over an eight week period. Formaldehyde samples were collected in two rooms (usually the kitchen or living room and bedroom) using personal sampling pumps (MSA Model G and Bendix BDX 44). Air was drawn through midget impingers containing 15-20 mls of a one percent sodium bisulfite absorbing reagent. Pumps were run at a flow rate of 0.7 L/minute for approximately one hour. Gas appliances were shut off and smoking was discouraged during the sampling period. Windows were closed approximately 1/2 hour prior to sampling. Quality control blanks were prepared to insure non-contamination of the absorbing solution. Samples were analyzed at the Wisconsin State Laboratory of Hygiene using a modified NIOSH chromotropic acid procedure (NIOSH, 1977).

These data along with climatologic and home environment data measured at the time of sampling were key punched to magnetic tape by data entry staff of the Wisconsin Division of Health. Statistical analyses were executed under version 79.5 of SAS (Statistical Analysis System, Inc., 1979).

A total of 979 household visits were made during the course of the study. Formaldehyde concentrations were found to range from below the limit of detection (0.10 ppm) to 2.84 ppm. The mean for this distribution was 0.46 ppm; the median was 0.39 ppm. The 75th percentile was 0.59 ppm, while the 90th percentile was 0.85 ppm. The distribution exhibited a marked positive skewness; taking the log transform of the readings resulted in a symmetrical normal distribution. Here, the geometric mean was 0.37 ppm.

The home age distribution exhibited a bimodal shape which reflected the age stratified sampling design of the study. Approximately 100 homes were less than 36 months old at enrollment into the study (58 homes were less than 12 months old). The remaining 37 homes had an average age of 67 months. Homes less than three years old had an average monthly formaldehyde reading of 0.54 ppm; homes over three years old averaged 0.19 ppm each month.

Thus, the hypothesis that conditional selection of dwellings by home age would yield a "high to low" gradient for the "new" (less than 3 years old) versus older (greater than 3 years old) homes was confirmed, indicating that the study selection methodology had accurately targeted onto the population at risk for exposure.

A. Quantification of Factors Influencing the Formaldehyde Concentration.

Prediction models for indoor formaldehyde concentrations were developed with indoor and outdoor temperature and humidity, and age of mobile home as independent variables.

Successive readings were first correlated to discern if dependency existed among the repeated measurements made in each home. High correlation between a reading and its lag would suggest a weighted least squares regression model as a more reliable approach to obtain predictor estimates (Draper and Smith, 1981). Correlations among successive home samples were examined for both uncorrected and temperature - humidity corrected (Berge and Hanetho, 1980) formaldehyde readings. No systematic pattern of correlation was observed for either the corrected or uncorrected readings. Least squares regression was thus employed to construct the prediction models.

Regressions were performed on both the arithmetic and log transform of the formaldehyde concentration values and home age; climatologic variables were not transformed. Transforming both concentration and age generated a more suitable linear scatter of data points for least square regression.

Stepwise regression analysis was performed for uncorrected formaldehyde readings with indoor and outdoor temperature and humidity and home age as independent variables. Home age and indoor temperature were selected as significant predictors of formaldehyde concentration in ppm. Log home age and indoor temperature were again selected as predictors for the log transform of the formaldehyde sample. Home age was selected first in both instances, exhibiting a negative relationship with the indoor concentration. Indoor temperature exhibited a positive association with formaldehdye concentrations. The interaction for home age and temperature was subsequently tested for and found to be significant.

Since temperature and humidity were corrected in the second analysis, only home age was examined as a predictor variable. Again, in both instances, home age demonstrated a significant negative relationship to the formaldehyde concentrations.

The uncorrected log formaldehyde prediction model exhibited the greatest R-Square value (approximately 46%); the R-Square for the corrected log formaldehyde model was 30%. The R-Square for corrected and uncorrected arithmetic formaldehyde models was 18% and 33% respectively.

Preliminary investigations of additional environmental parameters indicated that these predicative models may be improved, raising the R-Square by as much as 20%. Significant variables for additional consideration include the number of windows in the home, the number of windows open prior to sampling, wind speed, and households with occupants who smoked tobacco. (all appear to have a negative relationship to concentration). Humidity did demonstrate a positive coefficient for predicting formaldehyde, however, it did not reach statistical significance in this analysis. An improvement for predicting concentration with home age would undoubtedly be achieved with the quantitation of ventilation rates and particle board emitting source load (i.e., board area/room volume ratio).

Summary

The repeated measurement of mobile homes for formaldehyde failed to exhibit a systematic correlation between the sequential readings taken in each home. These data were thus analyzed using least squares regression, treating each sample as an independent observation. The log of the home age in months was seen to be the single best predictor of both climate corrected and uncorrected formaldehyde readings.

These findings are in accord with analyses previously performed on complaint case series and random pilot mobile home data (Dally et al., 1981). An improvement in these models' predictive power is suggested by the inclusion of variables that begin to quantify ventilation rates found in the home at the time of sampling. It is further hypothesized that accounting for source load will improve the models' efficacy.

B. Health Status Assessment

Health status assessment of mobile home residents was done to check possible associations of health effects with indoor formaldehyde concentrations. A monthly health status questionnaire and a one time chronic health questionnaire and clinical assessment were requested from all participants.

Subjects

A total of 339 persons were enrolled into the study. However, early dropouts yielded a cohort of approximately 288 persons which remained stable for six home visits. Ten percent of the persons were under two years old; the median age was 24 years

old. The 75th percentile was 35 years of age, while only 10 percent of the group were over 60 years old. Forty-eight percent were males, 52% were females. Roughly 37% were cigarette smokers.

Methods - Questionnaire

A total of 2,423 monthly health questionnaires were completed by the occupants. Symptoms queried included sensory and upper respiratory tract irritation, respiratory problems, and gastrointestinal disorders. The average monthly rate of response for these conditions (based on 2,404 responses) is depicted in Table 5.

TABLE 5

MONTHLY AVERAGE REPORT OF SYMPTOMS

Symptom	Percent Responding
Burning eyes	25%
Watery eyes	20%
Cough	44%
Runny nose	35%
Sneezing	43%
Dry throat	24%
Phlegm	25%
Wheezing	12%
Breathlessness	10%
Difficulty breathing	11%
Chest pain	8%
Swollen glands	6%
Headache	29%
Dizziness	10%
Weakness	10%
Tiredness	24%
Difficulty sleeping	16%
Nosebleeds	4%
Nausea	7%
Vomiting	5%
Diarrhea	10%
Fever	8%
Rash	11%
Other	1%

N=2,404

Higher rate of symptom report can be seen in the upper respiratory symptoms (cough - 44%; sneezing - 43%; runny nose - 35%) when compared to the remaining conditions. The irritant symptoms of burning and watery eyes, dry/sore throat, and phlegm center around a rate of 25%. Headache (29%) and tiredness (24%) are two neuro-behavioral conditions which also exhibit a relatively higher rate of report.

Stepwise logistic regression analysis (Cox, 1970) was utilized in order to examine the effect formaldehyde exposure, and the individual's age, sex, and smoking status would have on predicting the log odds of symptom report [i.e., P(symptom present)/P(symptom absent)]. Symptom logistic regression models were separately constructed for each of the months (April through December, 1980). Table 6 exhibits the results of the analyses. A coefficient is depicted if its sign remains unchanged and it achieves significance for at least three of the nine months of observation.

TABLE 6

SYMPTOM LOGISTIC REGRESSION MODELS
SIGNIFICANT REGRESSION COEFFICIENTS*
LOG FORMALDEHYDE AS EXPOSURE PARAMETER

Symptom	Log Formaldehyde	Age	Sex**	Smoking***
Burning eyes	+(8)	+(9)		
Watery eyes	+(7)	+(9)		
Cough				+(7)
Runny nose				
Sneezing				
Dry throat	+(3)			+(4)
Phlegm		+(9)		+(9)
Wheezing		+(3)		
Breathlessness		+(5)		
Difficulty breathing		+(5)		
Chest pain		+(6)		
Swollen glands	+(3)			
Headache			+(4)	+(7)
Dizziness		+(4)	+(4)	
Weakness		+(8)		
Tiredness		+(7)		
Difficulty sleeping		+(5)		
Nosebleed				
Nausea				
Vomiting				
Diarrhea	+(3)			
Fever				
Rash				

* Sign indicates direction of association. Number in parantheses indicates the number of months that the association remains significant ($P<0.05$)

** Sex: 0=male, 1-female

*** Smoking: 0=No, 1=Yes

As can be seen from the table, log formaldehyde concentration was associated with the report of burning and watery eyes, and dry sore throat. This is in accord with the known human responses to formaldehyde exposure (National Academy of Science, 1980; Schuck et. al., 1966; Kerfoot, 1975). The report of swollen glands and diarrhea also exhibit a log formaldehyde dependency. None of the other symptoms demonstrated a similar consistent relationship to formaldehyde.

Cigarette smoking exhibited a consistent positive relationship to the report of coughing, dry/sore throat, phlegm, and headache; smokers would thus have a higher rate of report than would non-smokers. Age was positively related to the report of burning and watery eyes, respiratory condition (phlegm, wheezing, breathlessness, difficulty breathing) chest pain, and several neuro-behavioral conditions (dizziness, weakness, tiredness, and difficulty sleeping). Sex predicted the report of headache, and dizziness.

Summary

A positive dependency of both burning eyes and watery eye symptom logits (log odds of report) on the log formaldehyde exposure parameter was demonstrated. In addition, a significant positive relationship with the respondent's age was also seen. Dry/sore throat, swollen glands and diarrhea logits exhibited a less robust dependency on formaldehyde exposure. The report of cough, phlegm, and headache were strongly related to cigarette smoking.

Increasing age was related to the log odds of symptom report in many instances because of the differential rate of response in younger persons. Continuing separate investigations of adult and children groups will factor out this pervasive effect to allow for an age-specific or stratified analysis.

Clinic and Chronic Health Assessments

After approximately six months, a more detailed comprehensive medical history, reproductive history and review of symptoms questionnaire was distributed and each study participant encouraged to attend one of three clinics for physical evaluation. The questionnaire asked each participant to subjectively assess each of the symptoms they had reported during the previous six months and record whether they felt the symptom was related to conditions in their home and whether they had experienced the same symptoms prior to moving into their current residence. The clinical evaluation focused on the eyes, nose, throat, respiratory system and skin looking for objective signs of irritation. The examining physicians did not know the levels of formaldehyde present in the homes of the

clinic participants. They were asked to review the participants current symptomatology and physical findings and report whether current upper respiratory infection or acute allergy reaction was present and whether the person was atopic. Spirometry and single breath diffusing capacity were performed on all participants over the age of 12. Clinics were conducted at the end of September and during the month of October to avoid the peak pollen allergy season and the winter flu season.

C. Adult Survey Participants

Prior to the distribution of the detailed questionnaires and the clinics, twenty-three households dropped out of the study. Explanations ranged from inconvenience of the monthly visits to three homes destroyed by tornados. Of the remaining 114 homes, 62% have returned their detailed questionnaires. Thirty-two households (28%) participated in the clinics. Utilizing the information of the monthly questionnaires, no differences were seen between the three groups, [1) non-responders, 2) returned questionnaires but not examined, 3) clinic participants] with regard to monthly prevalence of symptoms, age, sex and smoking habits. The mean formaldehyde level among the non-responder homes was significantly lower than either of the other groups (.37$\pm$ .2 ppm, .45$\pm$ .3 ppm, .49$\pm$ .2 ppm respectively). The adults who participated in the clinical examinations were significantly older than those who returned the questionnaires but were unable to be examined (39$\pm$ 19 years versus 31$\pm$ 14 years), although they were not older than the total group of not examined adults. All other parameters were similar between the two groups which returned the questionnaires.

Of the adults who returned questionnaires, 72% reported having experienced cough since the onset of the project and 58% had experienced eye burning. However, when asked if they thought the symptom was related to household conditions, only 11% of those with cough felt it was probable or definitely related. For eye burning, 71% felt it was related to the home. The presence of cough was not associated with the level of formaldehyde found in the home. However, individuals from homes with mean formaldehyde over .8 ppm felt their cough was related to the home environment significantly more frequently than those from homes with levels below .8 ppm (31% versus 7%). the occurrence of burning eyes was significantly associated with the level of formaldehyde found in the home. Utilizing the individual's subjective assessment strengthened this association even more. Not only did the prevalence of burning eyes increase significantly with increasing mean household formaldehyde, but also the proportion of individuals who felt their burning eyes were related to household conditions went from 50% to 87%. The mean household formaldehyde for those who felt their symptoms were related to their home was .59$\pm$ .3 ppm

and was .4± .2 ppm for those without symptoms or felt their symptoms were unrelated to home conditions. These means were statistically significantly different.

A total of 53 adults from 32 households completed the clinical examination portion of the study. Four individuals were determined by history and physical to have current "colds" and thus their clinical signs of eye and nose irritation were not attributable to formaldehyde exposure. They have been removed from this portion of the report. Thirty-six percent of those examined had a history of allergies. Signs of eye or nasal irritation were not significantly more prevalent among those with a history of allergy. Of the 49 adults, eighteen percent had mild to moderately injected conjunctiva and 14% had inflamed or congested nasal mucosa. Combined, 27% had evidence of mild to moderate mucosal irritation. Two individuals had nasal polyps (both predated moving into their mobile home). The prevalence of irritation signs correlated with increasing mean household formaldehyde (measurement closest to day of exam was utilized). Ten percent of individuals from households with less than .4 ppm formaldehyde had signs of irritation compared to 24% of those greater than .4 ppm. Of the 9 individuals from households with greater than .8 ppm, 5 (56%) had signs of irritation. The mean formaldehyde for those with signs of irritation was .7± .3 ppm compared to .4± .3 ppm for those without signs of irritation. This difference was statistically significant. Spirometry did not identify any associations other than those already well recognized for cigarette smoking.

VI. Summary of Laboratory Activities

The Clinical Chemistry Section of the State Laboratory of Hygiene (SLH) provided laboratory support during the project. Their primary tasks included:

1. Evaluation of analytical techniques for formaldehyde.
   a. Determine which method would be most appropriate.
   b. Adapt the procedure for SLH use.
   c. Assess the method's accuracy and precision.
2. Establishment of quality control procedures.
3. Analyze samples.

The method chosen by the SLH for formaldehyde analysis was the NIOSH P+CAM 125 method or chromotropic acid method. The method has been widely used and it had sufficient sensitivity and reproducibility for use in residential sampling. The procedure involves collection of air in two midget impingers connected in

series. In each impinger there is an absorbing reagent which forms a complex with formaldehyde as air is bubbled through the impinger. The liquid is analyzed in the laboratory. Chromotropic acid and sulfuric acid is added to an aliquot of the specimen to form a purple chromagen. The absorbance, read at 580 nm on a spectrophotometer, is proportional to the amount of formaldehyde in the solution.

Two major modifications were made in the NIOSH procedure. The method specifies that distilled water should be used as the absorbing reagent. However, with water there are potential sample stability problems. Several studies indicated that sodium bisulfite was more efficient at collecting formaldehyde and formed more stable complex with formaldehyde than distilled water. Since samples could not be analyzed immediately, a 1% sodium bisulfite solution was used as the absorbing reagent. The solutions were prepared in the field at two of the three field staff stations by mixing preweighed portions of sodium bisulfite and double distilled water. At the third location, field staff used solutions prepared by SLH.

The second major modification was in the standardization procedure. The NIOSH method recommends the use of a 37% formalin solution diluted in distilled water or sodium formaldehyde bisulfite in the standardization process. This is titrated against an iodine solution to obtain the formaldehyde concentration of the standard solution. However, the reproducibility of this method was not adequate for the determination of low levels of formaldehyde. The quality control labs used by SLH had experienced similar problems with this standardization procedure. The best laboratory agreement occurred when the same stock solutions were used by the various labs. As a result, the laboratory undertook an investigation of various standardization procedures to determine which method would be best. A method based on the titration of a stock solution by sodium sulfite was used. The stock solution was prepared by refluxing paraformaldehyde in water to form methylene glycol. The stock solution was then diluted in a 1% sodium bisulfite solution for the preparation of standard curves since samples were collected in sodium bisulfite. This method has since been published by NIOSH in 1981 as a replacement for the iodine titration method for P+CAM 125 (NIOSH, 1981).

A total of 1,874 air samples were analyzed during the main formaldehyde study.

Quality Control Procedures

Blanks: Two types of blanks were collected during the project. Sodium bisulfite blanks were prepared daily in the field to determine background concentrations of formaldehyde in the collection liquid. If more than one batch of sodium bisulfite was mixed and used per day, blanks were prepared from each.

Each batch mixed was identified by a unique identifying number and this was used to indicate which samples came from particular batches of the absorbing reagents. A total of 730 blanks were collected and analyzed.

Impinger blanks were also prepared to determine how adequately impingers were being rinsed between uses. Under ideal circumstances, impingers should be acid washed between each use for thorough cleansing. However, due to the large numbers of samples collected daily, the hazard of handling acid in the field and the location of field staff away from the lab, this could not take place. To ensure that carryover from sample to sample was minimal, a strict rinsing procedure was used to wash the impingers between each use. Before use, the impinger was washed three times with sodium bisulfite and three times with distilled water. Care was taken to fill the base entirely full of rinse water and to thoroughly rinse the stem.

Impinger blanks were prepared in the field by following the rinsing procedure and then adding 15 mls of liquid to the impinger, agitating it, and adding the contents to a sample vial. The blanks were prepared at least once per day. A total of 573 impinger blanks were collected and analyzed.

Sample Handling

Past experience at SLH indicated that certain types of bottle cap liners contained substances that interfered with the analysis. This has been confirmed by additional studies. To prevent contamination, Nalgene polyproplyene bottles were used to store samples. Several studies have indicated that sample loss can occur when samples are stored at room temperature. Samples could not be analyzed immediately, so special precautions were taken to ensure that sample loss was minimized during storage. The sodium bisulfite solutions were kept refrigerated until use and stored in ice chests in the field. All samples after collection were placed in ice chests and then stored in a refrigerator. When it was necessary to ship samples, specimens were placed in an insulated shipping container with frozen foam packs with overnight delivery to the SLH. Temperatures in the containers ranged from 9-12°C. upon arrival.

Quality Control Procedures

During each analysis, samples from the previous run were re-analyzed. These replicate samples included all sodium bisulfite blanks exceeding 0.20 µg/4 ml aliquot, all impinger blanks exceeding 0.5 µg/4 ml aliquot, all outdoor samples exceeding 0.1 ppm, specimens collected within the same home where the two room samples didn't agree within $\pm$ 0.10 ppm, and random selections of high, medium, and low specimens.

Assays from a pool solution was prepared and run in duplicate during each run. Other chemists also participated in analyses on several occasions. If deviations beyond the preestablished limits in standard curves were detected, analyses were repeated for all affected specimens.

During the project, samples were sent to other laboratories for inter-laboratory quality control. Samples were sent to RalTech Laboratory, Madison, Wisconsin three times during the main study. Samples were analyzed within 24 hours. When the same method of standardizing the stock standard was used, (sodium sulfite titration) excellent agreement was obtained between both laboratories - both with split laboratory prepared solutions and actual split air specimens. Agreement was not as good when different standardization techniques were used.

Precision and Accuracy Determination

In order to determine the precision and accuracy of the method used by the SLH, a study of pool solutions of known concentrations was conducted. Concentration levels of 0.20, 0.30, 0.40 and 5.50 µg/4 ml aliquot were chosen for study. This is equivalent to 0.01, 0.02, 0.03 and 0.40 ppm using our sample procedures. Ten replicate assays of each concentration were run daily for five days. Forty blank specimens were prepared each day and one was paired with a pool specimen.

Specimens could be distinguished from blanks and each other at each of the concentrations on the spectrophotometer. However, the coefficients of variation (CV) at the three lowest concentrations were quite high. The inter-run CV for the analysis ranged from 32% at 0.03 ppm to 125% at 0.01 ppm. At 0.40 ppm the CV was only 1%. Interday variations of spectrophotometer which reflect changes in sensitivity from day to day were significant, however, when the ppm value is calculated this difference shows up in the third or fourth decimal place.

Combining the CV's for the sampling and analytical procedures a total CV for the method was calculated. At 0.03 ppm the total CV was 32% while at 0.40 ppm the total CV was 5%. At 0.03 ppm the 95% confidence interval is 0.01 to 0.05 ppm while at 0.40 ppm it is 0.36 to 0.44 ppm. These represent the results from a single impinger analysis. When two impingers are used, the error will be slightly higher. At low concentrations (less than 0.10 ppm) values are subject to high relative error since the concentration from each of the two impingers used in the sample train are added together. Because of this, 0.10 is considered the overall detection limit of the method as used during the project.

VII. Other Related Projects

Follow-up Study

Occupants of homes originally investigated in 1977-79 were contacted in March-July, 1981 and asked to participate in a follow-up study. In addition to measuring formaldehyde, CO, respirable particles, and nitrogen dioxide were also measured to give a better indication of total indoor air quality. There were 27 homes in the group and these included 17 mobile homes, 5 conventional homes with particle board products, and 5 conventional homes with U-F foam insulation. The original group mean formaldehyde concentration was 0.58 ppm, while at the follow-up visit these homes had a mean of 0.30 ppm. This represented a significant decrease in formaldehyde concentration. This would be expected since the homes had increased in age on the average of 20.5 months. An interesting finding is that even after this increase in age of the home, the mobile homes still had a mean concentration of 0.37 ppm. As with our other formaldehyde studies, good correlation was found between samples collected in different rooms; and no affect in formaldehyde concentration was found from the presence of smokers or gas stoves.

Different sample collection techniques were utilized during this study. Samples were collected side by side in distilled water with impingers immersed in an ice bath, sodium bisulfite with impingers immersed in an ice bath, and sodium bisulfite with impingers not immersed in an ice bath (conventional method). No significant difference in formaldehyde concentration was found between the collection methods.

In addition, the samples collected in distilled water were also analyzed using the pararosaniline method as modified by Lawrence Berkeley Laboratory, Berkeley, California (Miksch et al., 1981). The method was not available for evaluation until after the main study had been completed. Since the pararosaniline method was reported to be more sensitive to lower formaldehyde concentrations, we evaluated it here to determine whether it could be used for future projects. The correlation, however, between samples analyzed by this method and by the chromotropic acid method was not very good. It appeared that SO_2 emitted from the impingers using sodium bisulfite may have been a serious interferent with the pararosaniline method (Eckmann et al., 1982).

Nitrogen dioxide concentrations ranged from none detected to 156.6 $\mu g/m^3$. Homes with gas stoves had a mean kitchen concentration of 64.9 $\mu g/m^3$, while homes with electric stoves had a mean kitchen concentration of 8.0 $\mu g/m^3$. These findings are similar to those found in studies by other researchers. Respirable particle concentrations ranged from 0.005 $\mu g/m^3$ to 1.570 $\mu g/m^3$. Homes with smokers had levels higher than homes without smokers. Carbon monoxide concentrations ranged from none detected to about 10 ppm.

Comparison of Passive Monitors with NIOSH Method

Three homes were visited in an effort to compare two dosimeters with the impinger method of collecting formaldehyde. Since the dosimeters were exposed for eight hours, eight sequential 1-hour samples were collected in impingers to cover the entire time period the dosimeters were exposed. Three DuPont passive monitors and two Envirotech dosimeters were placed in the kitchen and in two bedrooms. In the kitchen and one bedroom two sample trains with impingers were set up side by side, and in the third bedroom one sample train was set up.

All the impinger samples were analyzed using the chromotropic acid procedure; the DuPont badges were analyzed by the Indiana Board of Health Lab in Indianapolis using the chromotropic acid method and the Envirotech dosimeters were sent back to the distribution for analysis.

The correlation between the passive monitors and the impinger samples was not very good. One problem with the DuPont monitor was probably insufficient sample time indicating that an eight hour exposure of this badge at relatively low concentrations is not adequate to detect the levels actually present in a home. It was discovered later that the Envirotech badges had some design flaws necessitating modification, so results from the dosimeters used here are probably not valid.

Despite the problems with the passive monitors, the study was useful in that many samples taken by one person over an eight hour time period in different rooms could be compared. While data analysis is not complete at this time, correlation between the samples is good. Given that the home was sampled under relatively constant temperature conditions, little variability in sample results was seen.

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